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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,372	04/09/2001	Morten Peter Meldal	11225.13US01	9680

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EXAMINER

BAKER, MAURIE GARCIA

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 09/10/2002 7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/829,372	Applicant(s) Meldal et al
Examiner Maurie G. Baker, Ph.D.	Art Unit 1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Dec 18, 2001

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-47 is/are pending in the application

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims 1-47 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. The Preliminary Amendment filed December 18, 2001 is noted. Claim 1 was amended and no claims were added or cancelled. Therefore, claims 1-47 are currently under consideration.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, drawn to a method of forming an intermediate compound, classified in various classes and subclasses depending on the structure of the intermediate compound, for example, class 530, subclass 338.
- II. Claims 10-19, drawn to a method of preparing target compounds, classified in various classes and subclasses depending on the structure of the target compounds, for example, class 436, subclass 528.
- III. Claims 20-27, drawn to a compound consisting of a “template molecule” and “protection groups”, classified in various classes and subclasses depending on the structure of the compound, for example, class 562, subclasses 553-576.
- IV. Claims 28-37, drawn to a compound “prepared according to the method of claim 10”, classified in various classes and subclasses depending on the structure of the compound, for example, class 424, subclass 194.1.

- V. Claims 38-46, drawn to a method of using protection groups to produce microarrays, classified in various classes and subclasses depending on the nature of the microarray, for example, class 536, subclass 25.3 or class 435, DIG 49.
- VI. Claim 47, drawn to a method for biomolecular screening, classified in various classes and subclasses depending on the specific screening steps, for example, class 435, subclass 7.1 or DIG 14-19.

3. The inventions are distinct, each from the other because of the following reasons:

4. Groups I, II, V and VI are different methods. The methods are different because they use different steps, require different reagents and will produce different products and/or results. They therefore have different issues regarding patentability and enablement and represent patentably distinct subject matter. The differences are discussed in detail below.

5. First, in the instant case, the methods of Groups I and II are different from each other as the method of Group II requires a “protected template molecule” that is not present in the method of Group I. Thus the products made by the two methods are different (different end results). The methods also have different steps. It is noted that the methods of Groups I and II make an intermediate and final product; however, the methods of making these molecules are different as set forth above. Moreover, the intermediate product made by the method of Group I would be useful to make other than the final product (see MPEP § 806.04(b), 3rd paragraph). Furthermore, the methods of

Groups I and II are different from the methods of Groups V and VI as Groups V and VI are methods of making/use involving microarrays.

6. The methods of Groups V and VI are different from each other as Group V is a method using protection groups to produce microarrays, while Group VI is a method for biomolecular screening. These methods produce completely different end results (method of making an array versus method of screening an array) and thus are patentably distinct subject matter.

7. Groups III and IV represent separate and distinct products. They differ in respect to their properties, their use and the synthetic methodology for making them. Therefore, they have different issues regarding patentability and enablement and represent patentably distinct subject matter. In the instant case, the compound of Group III consists of a “template molecule” and “protection groups”, while the compound of Group IV (i.e. a compound “prepared according to the method of claim 10”) has a “template molecule” and “protection groups” and *target groups*. The presence of different structural elements between the two compounds indicates that they are different in structure, properties, etc. as set forth above and thus represent different inventions.

8. Groups II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the

product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the compounds of Group IV could be made by a different process than that of Group II; for example, the compounds could be made by solid phase synthesis using traditional orthogonal protection.

9. Groups III and IV are not related to Groups V and VI. The inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. In the instant case the *compounds* of Groups III and IV are not related to the methods of making or using *microarrays* (Groups V and VI).

10. Furthermore, Group VI is not related to Group I as the compound of Group VI is not made by the method of Group I. In the same manner, Group III is not related to either of Groups I or II as the compound of Group III is not made by the methods of Groups I or II (the compounds of Group III do not contain target groups).

11. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

12. This application contains claims directed to patentably distinct species of the claimed invention for **Groups I – V**. Election is required as follows.

13. If applicant elects the invention of **Group I**, applicant is required to elect from the following patentably distinct species. Please elect one species from *each* subgroup below. Claim 1 is generic.

Subgroup A: Species of building block units (e.g. claims 4-9)

Applicant is required to elect, for purposes of search, specific building blocks. The election should result in a single, specific chemical structure.

Subgroup B: Species of linkage (e.g. claims 2, 3)

Applicant is required to elect, for purposes of search, a specific type of linkage from those set forth in the claims.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

14. If applicant elects the invention of **Group II**, applicant is required to elect from the following patentably distinct species. Please elect one species from *each* subgroup below. Claim 10 is generic.

Subgroup A: Species of building block units (e.g. claim 13)

Applicant is required to elect, for purposes of search, specific building blocks. The election should result in a single, specific chemical structure.

Subgroup B: Species of linkage (e.g. claims 11, 12)

Applicant is required to elect, for purposes of search, a specific type of linkage from those set forth in the claims.

Subgroup C: Species of template molecule (e.g. claims 14-19)

Applicant is required to elect, for purposes of search, a specific template molecule. The election should result in a single, specific chemical structure and should be completely defined. That is, the type of functional

group (e.g. claim 14), specific type (e.g. claims 15, 17-19) and whether or not it is attached to a resin (e.g. claim 16) should all be defined.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

15. If applicant elects the invention of **Group III**, applicant is required to elect from the following patentably distinct species. Please elect one species from *each* subgroup below. Claim 20 is generic.

Subgroup A: Species of protection group (e.g. claims 23-27)

Applicant is required to elect, for purposes of search, a specific protection group. The election should result in a single, specific chemical structure with all portions (i.e. building blocks) defined.

Subgroup B: Species of template molecule (e.g. claims 21, 22)

Applicant is required to elect, for purposes of search, a specific template molecule. The election should result in a single, specific chemical structure and should be completely defined. That is, the type of functional group (e.g. claim 21), specific type (e.g. claim 22), etc. should all be defined.

Note that the elections above should result in the election of a single compound species with all variable groups defined. All atoms and bonds of the single elected compound species should be shown.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

16. If applicant elects the invention of **Group IV**, applicant is required to elect from the following patentably distinct species. Please elect one species from *each* subgroup below. Claim 28 is generic.

Subgroup A: Species of compound; elect one of the following

A1: Multiple antigen peptide; claims 29-32

A2: De novo protein; claims 33-37

Subgroup B: Species of template molecule and other portions of the compound

Applicant is required to elect, for purposes of search, a specific template molecule and specific "target groups" or "functional secondary structure". The election should result in a single, specific chemical structure and should be completely defined.

Note that the elections above should result in the election of a single compound species with all variable groups defined. All atoms and bonds of the single elected compound species should be shown.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

17. If applicant elects the invention of **Group V**, applicant is required to elect from the following patentably distinct species. Please elect one species from *each* subgroup below. Claim 38 is generic.

Subgroup A: Species of protection group

Applicant is required to elect, for purposes of search, a specific protection group. The election should result in a single, specific chemical structure with all portions (i.e. building blocks) defined.

Subgroup B: Species of target group (e.g. claims 39-43)

Applicant is required to elect, for purposes of search, a specific type of target group.

Subgroup B: Species of solid support (e.g. claims 44-46)

Applicant is required to elect, for purposes of search, a specific type of solid support.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

18. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

19. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and *a listing of all claims readable thereon*, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

20. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

21. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

22. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

23. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

24. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday from 9:00 to 6:30 and alternate Fridays.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (703) 308-4537. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
September 5, 2002



MAURIE GARCIA BAKER, Ph.D.
PATENT EXAMINER



RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

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ART UNIT: 1627

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